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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,980	02/21/2002	John N. Feder	D0121 NP	9974

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,980	FEDER ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-29,31-37,40 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-29, 31-37, 40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Amendment and Response of 8 January 2004 filed in response to the Non-Final Office Action mailed 22 September 2003. Claims 20-41 were considered in the 22 September Office Action. Claims 30, 38 and 39 were canceled and claims 20, 24 and 26 were amended in the 8 January Paper. Claims 20-29, 31-37, 40 and 41 are pending and under consideration.

Response to Amendment

Claim Rejections - 35 USC § 112

Rejection of claims 20, 31-37, 40 and 41 under 35 U.S.C. 112, first paragraph, as lacking adequate written description is withdrawn in view of the amendments to the claims such that they are limited to nucleic acids having explicitly described structure.

Claims 20-29, 31-37, 40 and 41 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record and herein below in the response to arguments.

Rejection of claims 24 and 26 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claims.

Double Patenting

Regarding the potential objection to claim 39 under 37 CFR 1.75 as being a substantial duplicate claim 35, the issue is rendered moot by the cancellation of claim 39. It is noted, however, that claims 40 and 41 appear to be duplicates of claims 36 and 37 and, should claims 36 and 37 be allowed, claims 40 and 41 will be objected to as substantial duplicates. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101 and 112, first paragraph

Claims 20-29, 31-37, 40 and 41 stand rejected under 35 U.S.C. 101 and 112, first paragraph, because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for reasons of record and herein below in the response to arguments.

Response to Arguments

Claim Rejections - 35 USC § 112

In response to the arguments of record, Applicant states that previous arguments are reiterated. These arguments are fully addressed in previous Office Actions.

In response to the Examiner's assertion that the disclosure provides no suggestion of what the proposed assays will be used for other than to diagnose or treat some unspecified disease, Applicant argues that an extensive list of specific diseases and conditions are provided in the specification. Applicant urges, "[t]hese diseases and conditions are discussed by a specific

name, and are not presented as generalized states" (bridging pages 6-7). This argument is not found persuasive because a list of candidate conditions is not a specific teaching. The first paragraph of 35 U.S.C. §112 requires that the specification contain a written description of the manner and process of using the invention in full, clear, concise, and exact terms. Applicant seems to be arguing that a specific teaching requires only that the applicant use proper nouns when speculating on what one might do with the invention. On the contrary, a full, clear, concise and exact teaching must distinguish those conditions that can be diagnosed and treated from those conditions that cannot be diagnosed and treated, and must also teach how to carry out the diagnosis and treatment. Clearly the instant specification fails to do this.

Applicant also urges that *In re Wands* supports their contention that routine experimentation, regardless of the amount, does not render a claim incompliant with 35 U.S.C. §112, first paragraph. Applicant's interpretation of the cited passage seems overly generous. As quoted by Applicant, the Court states, "The test is *not merely quantitative*, since a *considerable amount* of experimentation is permissible..." (quoted at page 7 of the remarks filed 22 December 2003; emphasis added). This statement does not support Applicants contention that the amount of "routine experimentation" is irrelevant to the enablement inquiry. The proper interpretation of the Court's statement is that determination of enablement does not exclude consideration of the quantity of experimentation, but goes beyond this single consideration. With regard to the legal standard for "undue experimentation", *In re Wands* is clear, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* ...They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working

examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims" (8 USPQ2d 1400, page 1404; emphasis added).

Thus, the Court clearly indicates that quantity of experimentation is a factor to be considered. Furthermore, complete analysis of the instant claims according to the "Forman factors" is clearly set forth in the Office Action mailed 18 November 2002, and the arguments and evidence provided by Applicant to rebut the *prima facie* case have been found unpersuasive for the reasons set forth in several subsequent Office Actions. Thus, the claims have been found to lack enablement not only because of the amount of experimentation required, although this is a factor, but based on a complete analysis of the disclosure according to the factual inquiry set forth in *Ex parte Forman*.

Applicant's arguments have been fully considered but are not deemed persuasive individually or as a whole; therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement.

Claim Rejections - 35 USC § 101

Claims 20-29, 31-37, 40 and 41 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

In response to the *prima facie* case, Applicant argues that the specification does, in fact, disclose specific disorders associated with altered levels of the K^+betaM6 and cites a passages in the specification which teach that agonists and/or antagonists for K^+betaM6 can be used to treat

epilepsy, Bartter's syndrome, persistent hyperinsulinemic hypoglycemia of infancy, hyperkalemia and hypokalemia, cystic fibrosis, hypercalciuric nephrolithiasis, rheumatoid arthritis, asthma, multiple sclerosis and osteoarthritis. Applicant additionally urges that these diseases are only representative, and additional diseases and conditions are provided in the specification. As discussed above, however, a list of candidates is not a specific teaching. It is extremely unlikely that even a significant fraction of the diseases listed in the specification could actually be diagnosed or treated using the claimed invention or methods and pharmaceuticals developed therewith. Therefore the teachings do not constitute a specific utility, but are instead an invitation to experiment and discover which, if any, of the suggested conditions might be diagnosed or treated according to the teachings of the specification.

Next, Applicant cites Example 6 and contends that results obtained with an alleged insect ortholog of the claimed invention indicate that the claimed sequence is likely to have a function in the modulation of one or more mammalian immune pathways. However, even if one were to assume, *arguendo*, that the insect sequence is an orthologue of the claimed sequence, data suggesting some involvement of a distantly related protein in innate immunity in *Drosophila* does not amount to a specific teaching of how the instant protein can be used.

Applicant argues that the asserted utilities are substantial because the specification indicates various conditions in which modulation of the expression of the claimed sequence can be employed to diagnose, treat and/or prevent, as well as guidance in how to achieve the desired results. This argument is not deemed persuasive because, with regard to application of the claimed sequence, the teachings of the specification merely provide avenues for further research.

The MPEP states, "[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' utility are not substantial utilities" (see M.P.E.P. 2107.01 (I)).

With regard to the Examiner's assertion that the specification fails to establish the functional properties of the claimed invention, Applicant again submits that the homology data provided in the specification support the asserted function as a Maxi-K potassium channel. The homology data have been discussed in several previous Office Actions. To summarize, the specification asserts that the claimed polynucleotide encodes a MaxiK channel beta subunit based on very limited homology to a single protein having established function and homology with several other proteins which do not have an established function. MaxiK channel β-subunits are highly conserved, having 71% identity over the full length of the protein across species, while the instant protein has 0% identity to a MaxiK channel β-subunit. In the case of the proteins having less than 50% identity, the art cited in previous Office Actions teaches that a related function would not be expected unless it could be established that the proteins comprised regions of high identity that could be correlated with a known function. Given the unconfirmed nature of the asserted function, and because the asserted utility for the claimed nucleic acid is based on the predicted function, one skilled in the art would have to perform additional experimentation to identify and/or reasonably confirm the functional characteristics of the claimed invention. Therefore, the asserted utility would not be considered substantial.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected under 35 U.S.C. § 101 and 112, first paragraph.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID GUZO
PRIMARY EXAMINER